

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: <u>D453428</u>; FILE SYMBOL/REG. No.: <u>42750-GTE</u>; PRODUCT NAME: <u>Lambda</u>

Cyhalothrin Technical; DECISION No.: 551655; PC Code(s): 128897; ACTION CODE: R333; FOOD Use:

Yes; REGISTRANT: Albaugh, LLC

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATE: March 25, 2020

SUBJECT: Product Chemistry Review of "Lambda Cyhalothrin Technical"

FROM: Shyam Mathur, Ph.D; Product Chemistry Team Leader, CITAB/RD(7505P) somathur 3-3-20

THROUGH: Kerry Leifer, Branch Chief, CITAB/RD (7505P) KERRY LEIFER Digitally signed by KERRY LEIFER Date: 2020.04.01 15:44:01 -04/00'

TO: Helen Hull-Sanders / Catherine Aubee, I-V Branch1 / RD (7505P)

Active Ingredient(s): Lambda Cyhalothrin (96.6%); Product label Claim: 96.6%

MRID No(s).: Submitted - 50850201 (Summary of product chemistry data)

50850202 (group B data) 50850203 (group A data)

Deficiencies: Yes

CONCLUSION:

Group A: Acceptable - All required data submitted to support the proposed basic CSF (dated: June 3, 2019)

Group B: Acceptable – Except for the guidelines

830.6313 - (study is required to determine stability of TGAI/MUP against metal & metal ions at RT & at elevated temperatures (54°

830.6314 – (study is required to determine compatibility/non-compatibility of TGAI/MUP with respect commonly used chemicals (oxidizing/reducing agents; MAP, organic solvent, water etc)

830.6317 – (one year or accelerated study must be conducted to determine the stability of TGAI/MUP using commercial container)

830.6320 - (one year or accelerated study must be conducted to determine the stability of TGAI/MUP using commercial container)

Results of these must be submitted to the Agency for evaluation.

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CSF:

Proposed Basic CSF: (96.6%, dated: June 3, 2019;

- Acceptable

[Supporting 5-batch analysis results are provided on page # 16 of this report]

Alternate CSF's in compliance with 40CFR§152.43: Yes []; No []; NA [x]

Similarity from chemistry point of view - to cited product with Reg. No.100-1013:

Similar []; Not similar [X]; Identical []; Not applicable []

Note:

- <u>1.</u> The nominal concentrations of the active ingredient are significantly different [96.6% in proposed product vs 89.0% in cited product]
- 2. Impurity profile of two products are significantly different.

Product label: Recommendations: Yes []; No [X]; NA []

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Yes; REGISTRANT: Albaugh, LLC

830.1550 (product identity & composition) [MRID No. 50850203]

Common Name: Lamda Cyhalothrin

IUPAC Name: Mixture of isomers (R)- α -cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-

3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate

OR

Mixture of isomers (R)- α -cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-

trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate

C.A. Name: (R)-cyano(3-phenoxyphenyl)methyl (1S,3S)-rel-3-[(1Z)-2-chloro-3,3,3-

trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate

CAS Registry Number: 91465-08-6 Molecular Formula: $C_{23}H_{19}CIF_3NO_3$ Molecular Weight: 449.85

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Manufacturing facility:



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830.1800 (enforcement analytical method) [MRID No. 50850204]

The content of the active ingredient cyhalothrin was determined by GC-FID method with internal standard calibration method. The GC-FID was operating under following parameters

The active ingredient content in test item was determined under the chromatographic conditions given below:

Instrument : Gas Chromatograph equipped with

Flame Ionization Detector and PC based

data system

Column : ZB-1, 30 m long, 0.25 mm i.d., 0.1 μm

film thickness

Injection System

Injector : Split injection

Split Ratio : 100:1

Temperatures

Injector : 300°C

Detector : 300°C

Column Oven : 213°C

Gas Flow Rates

Helium (Carrier) : 1.0 mL/min. Hydrogen : 30 mL/min. Air : 300 mL/min. Helium (make up) : 30 mL/min.

Volume of Injection : 1 μL

The analytical method used for the determination of Lambda Cyhalothrin (a.i.) content in the test item was validated by establishing specificity and selectivity, linearity, range, precision, robustness, intermediate precision and accuracy as detailed below.

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Group B Product chemistry data (physical-chemical characteristics)

[MRID No. 50850201 and 50850202]

GLN	Requirement	MRID	Status	Result or Deficiency		
830.6302	Color	50850201 50850202	A	Cream colored (Munsell color scale: 5Y 9/1)		
830.6303	Physical state	50850201 50850202	A	Crystalline Solid		
830.6304	Odor	50850201 50850202	А	Mild plastic odor		
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions	50850201 50850202	G	The registrant is required to conduct this study and the results must be submitted to the Agency for evaluation.		
830.6314	Oxidation/reduction: chemical incompatibility	50850201 50850202	G	The registrant is required to conduct this study (compatibility/non-compatibility with commonly use chemicals) on TGA/MUP and the results must be submitted to the Agency for evaluation.		
830.6315	Flammability	50850201 50850202	NA			
830.6316	Explodability	50850201 50850202	NA			
830.6317	One Year or Accelerated storage stability	50850201 50850202	G	One year or accelerated study must be conducted on TGAI/MUP and the results must be submitted to the Agency		
830.6319	Miscibility	50850201 50850202	N/A	The product is a solid.		
830.6320	One Year or Accelerated corrosion characteristics	50850201 50850202	G	One year or accelerated study must be conducted on TGAI/MUP and the results must be submitted to the Agency		
830.7000	pH	50850201 50850202	А	7.31 at 20.2°C		
830.7050	UV/Visible absorption	50850201 50850202	Cited Literature*1	Conditions	λ (nm)	ε (L/mol.cm)
				Neutral (MeOH: 99% w/w)	254 277	1090 2070

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Table 2: Physical and Chemical Properties for "Lambda Cyhalothrin Technical"						
GLN	Requirement	MRID	Status	Result or Deficiency		
830.7100	Viscosity	50850201 50850202	N/A	The product is a solid.		
830.7200	Melting point	50850201 50850202	А	49.5°C		
830.7220	Boiling point	50850201 50850202	N/A	The product is a solid.		
830.7300	Density	50850201 50850202	А	1.326 g/mL at 20.0°C		
830.7370	Dissociation constants in water (DC)	50850201 50850202	NA Cited *2	TS does not dissociate in water		
830.7550	Partition coefficient	50850201 50850202	A Cited*3	Log Pow = 7 @ 20.0°C		
830.7840	Water solubility	50850201 50850202	A Cited*3	Water solubility at 20.0 \pm 0.5°C: 0.005 mg/L (pH 6.5);		
830.7950	Vapor pressure	50850201 50850202	A Cited*3	2×10^{-4} Pa (at 20°C; est.) 2×10^{-1} Pa (at 60°C, interpolated)		

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers

^{*1-} Refer to University of Hertfordshire, Pesticide Properties Database. *Metribuzin*. Retrieved from https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/78.htm

^{*2.} Refer to University of Hertfordshire, Pesticide Properties Database. *Lambda cyhalothrin*. Retrieved from https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/415.htm

^{*3.} MacBean, C. (2012). The Pesticide Manual, Sixteenth Edition, page 269

